

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

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MENGYAO HU,	*
	*
Petitioner,	* No. 19-327V
	*
	*
v.	* Filed: September 23, 2022
	*
SECRETARY OF HEALTH	*
AND HUMAN SERVICES,	* Attorneys' fees and costs;
	*
	reasonable basis.
Respondent.	*
	*

* * * * *

Renee Gentry, Vaccine Injury Clinic – George Washington Univ. Law School, Washington, D.C., for petitioner;
Jennifer Shah, United States Dep’t of Justice, Washington, D.C., for respondent.

PUBLISHED DECISION DENYING ATTORNEYS' FEES AND COSTS¹

Ms. Hu alleged that the human papilloma virus (“HPV”) vaccine caused her to suffer myofasciitis. Ms. Hu was found not entitled to compensation. Decision, issued Sept. 7, 2021, 2021 WL 4447333.

Ms. Hu seeks an award of attorneys' fees and costs. The Secretary has objected because Ms. Hu has not satisfied a pre-requisite, a showing that reasonable basis supported the claim set forth in the petition. Because the Secretary's argument is persuasive, Ms. Hu's motion for an award of attorneys' fees and costs is DENIED.

¹ The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

I. Abbreviated Medical History

Ms. Hu was born in 1991. Exhibit 4 (damages affidavit) ¶ 1. In August 2014, Ms. Hu left China and came to the United States to pursue a degree at Boston University. Exhibit 6 (affidavit) ¶ 1.

In November 2014 and February 2015, Ms. Hu received the first two doses of an HPV vaccine. Exhibit 1 at 2. According to a record created in 2017, Ms. Hu had pain in her arms in 2015. Exhibit 3 at 60. Ms. Hu averred that the pain she felt after these two vaccinations was “superficial.” Exhibit 6 (affidavit, signed Oct. 30, 2020).

Ms. Hu received the third dose of an HPV vaccine on August 19, 2015. Exhibit 1 at 2. She alleges the August 19, 2015 HPV vaccine harmed her. Ms. Hu departed the United States for China later in August 2015. Exhibit 6 at page 2.

According to a medical record created on November 9, 2017, Ms. Hu experienced pain in her left arm in April 2016. Exhibit 3 at 60.² However, there are not medical records from April 2016 that corroborate this account.

In December 2016, Ms. Hu, who was still residing in China, stated she started having hand pain in November 2016. Exhibit 3 at 8. Ms. Hu confirmed the accuracy of this account. Exhibit 6 at page 2. The rheumatologist who examined her suspected that she might be suffering from either erythema nodosum or arthritis. Exhibit 3 at 8.

The next medical records come from October 2017. See Resp’t’s Rep. at 2. A record from this time suggests Ms. Hu might suffer from myositis. Exhibit 3 at 12. After a muscle biopsy on November 14, 2017 (Exhibit 3 at 24), a doctor proposed that Ms. Hu suffered from myofasciitis. Id. at 61-62.

While Ms. Hu filed other medical records reflecting her health through February 2019, those events are not relevant to the assessment of reasonable basis. For a summary of those medical records, see Resp’t’s Rep. at 3-5.

² This document is a translation of material originally written in Chinese.

II. Procedural History

Represented by Ms. Renee Gentry, Ms. Hu alleged that she suffered from myofasciitis and other injuries as a result of the HPV vaccine she received on August 19, 2015. See Pet., filed Mar. 1, 2019. Ms. Hu filed some initial medical records on March 18, 2019. Subsequently, she filed some more medical records as well as certified translated copies on September 10, 2019.

The Secretary reviewed this material. The Secretary maintained that the medical records submitted do not establish that she suffered myofasciitis. Resp't's Rep., filed Apr. 20, 2020, at 7. In addition, respondent questioned the temporal relationship as it appears that petitioner's joint pain began in November 2016, approximately 15 months after the vaccination. Id., citing exhibit 3 at 2. A status conference was held on April 27, 2020 to discuss respondent's report and the resulting order required Ms. Hu to file an onset/fact affidavit and answer specific narrative questions. See order, filed Apr. 28, 2020.

Although Ms. Hu filed an affidavit on August 4, 2020, she did not answer the specific narrative questions and was re-ordered to complete those questions. See order, filed Sept. 9, 2020. Subsequently, Ms. Hu filed her affidavit on October 31, 2020. Affidavits from her parents were filed November 6, 2020. More translated medical records were filed on December 29, 2020.

Ms. Hu was directed to file her expert report(s) by March 29, 2021. Order, issued Jan. 28, 2021. In a May 24, 2021 motion for enlargement of time, Ms. Gentry represented that although she communicated with numerous potential experts, none were willing to testify. Although given additional time to produce an expert report, petitioner did not. Ms. Gentry reported on June 24, 2021 that she had been unable to contact Ms. Hu for multiple months.

On June 30, 2021, a status conference was held to discuss whether Ms. Hu would file an expert report and next steps. Ms. Gentry described extensive unsuccessful efforts to communicate with Ms. Hu.

The same day, Ms. Hu was ordered to show cause as to why her case should not be dismissed by July 30, 2021 and to file an expert report by August 30, 2021. Counsel for Ms. Hu filed a status report on July 30, 2021, indicating that she had been unable to locate or contact Ms. Hu and thus would be unable to continue with this case. Ms. Hu did not file an expert report.

Ms. Hu's claim was denied. The grounds for dismissal were that Ms. Hu appeared uninterested in continuing her case and the evidence that she submitted was not sufficient to establish that she was entitled to compensation. Decision, issued Sept. 7, 2021.

Acting through Ms. Gentry, Ms. Hu sought an award of attorneys' fees and costs. Pet'r's Mot., filed Nov. 9, 2021. The motion consists of a single page (plus accompanying documentation regarding the amount requested). The motion did not present any argument as to how Ms. Hu qualifies for an award of attorneys' fees and costs.

The Secretary opposed an award of attorneys' fees and costs. Resp't's Resp., filed Nov. 23, 2021. The Secretary maintained that Ms. Hu's claim lacked reasonable basis for multiple reasons. The Secretary argued that the doctors did not entirely agree as to whether Ms. Hu suffered the condition (myofasciitis) for which she sought compensation. The Secretary also maintained that the onset of her symptoms did not occur, according to Ms. Hu's affidavit, until April 2016, which is approximately eight months after the third dose of the HPV vaccination. Next, the Secretary contended that neither a treating doctor nor a retained expert opined that the vaccination harmed Ms. Hu. Finally, the Secretary noted a lack of literature supporting the claims that an HPV vaccine can cause either myofasciitis or myositis. *Id.* at 5-6.

Again acting through Ms. Gentry, Ms. Hu addressed the issue of reasonable basis, at least in part. Pet'r's Reply, filed Nov. 29, 2021. Ms. Hu cited cases regarding the standards by which special masters should consider reasonable basis and presented some aspects of the procedural history of her case. Ms. Hu also maintained that some doctors diagnosed her with myositis. *Id.* at 2, citing exhibit 3 at 61-62 and exhibit 9 at 2, 6, 8-30. Ms. Hu also cited two cases in which the parties settled claims that an HPV vaccine caused myofasciitis.

With the submission of Ms. Hu's reply, the motion is ready for consideration.

III. Standards for Adjudication

Petitioners who have not been awarded compensation (like Ms. Hu here) are eligible for an award of attorneys' fees and costs when "the petition was brought in good faith and there was a reasonable basis for the claim." 42 U.S.C. § 300aa-15(e)(1). As the Federal Circuit has stated, "good faith" and "reasonable basis" are

two separate elements that must be met for a petitioner to be eligible for attorneys' fees and costs. Simmons v. Sec'y of Health & Hum. Servs., 875 F.3d 632, 635 (Fed. Cir. 2017). Here, the Secretary has not raised a challenge to Ms. Hu's good faith. Thus, the disputed issue is reasonable basis.

In Cottingham v. Sec'y of Health & Hum. Servs., the Federal Circuit stated that the evidentiary burden for meeting the reasonable basis standard "is lower than the preponderant evidence standard." 971 F.3d 1337, 1346 (Fed. Cir. 2020).³ Something "more than a mere scintilla" might satisfy the reasonable basis standard. Id. at 1346. Petitioners meet their evidentiary burden with "objective evidence." Id. at 1344. In categorizing medical records as objective evidence, the Federal Circuit stated, "[m]edical records can support causation even where the records provide only circumstantial evidence of causation." Id. at 1346. Finally, the Federal Circuit in Cottingham specified that "we make no determination on the weight of the objective evidence in the record or whether that evidence establishes reasonable basis, for these are factual findings for the Special Master and not this court." Id. at 1347.

In its most recent opinion regarding the reasonable basis standard, the Federal Circuit stated that medical records, affidavits, and sworn testimony all constitute objective evidence that could support reasonable basis. James-Cornelius v. Sec'y of Health & Hum. Servs., 984 F.3d 1374, 1379-81 (2021). The Federal Circuit further clarified that "absence of an express medical opinion on causation is not necessarily dispositive of whether a claim has reasonable basis, especially when the case is in its early stages and counsel may not have had the opportunity to retain qualified experts." Id. at 1379 (citing Cottingham VII, 971 F.3d at 1346). These two most recent decisions guide the analysis regarding what types of evidence constitute objective evidence of reasonable basis, as originally articulated in Simmons, though the ultimate weighing of such evidence is left up to the special master.

One judge of the Court of Federal Claims has explained that in the context of vaccine injury, "causation is defined by the Althen prongs" and "[b]y extension, the Althen prongs may provide at least some definitional context to causation in a reasonable basis analysis." Cottingham v. Sec'y of Health & Hum. Servs., 159

³ The Federal Circuit's precedential opinion is referred to as Cottingham VII.

Fed. Cl. 328, 334-35 (2022), appeal docketed, No. 22-1737 (Fed. Cir. Apr. 28, 2022).⁴ Merely pointing to some evidence of a causal relationship between a vaccine and an injury is not necessarily sufficient to establish reasonable basis because evaluating the weight of objective evidence and whether it constitutes reasonable basis is a decision for the special master. Id. at 335 (citing Cottingham VII, 971 F.3d at 1346).

IV. Analysis

Ms. Hu has not carried her burden to establish the reasonable basis for her claim that the third HPV vaccination caused her to suffer myofasciitis. Importantly, this burden is less than a showing of preponderant evidence. But, even at a lower (and, therefore, more easily satisfied) standard, Ms. Hu’s objective proof falls short.

While the Secretary presented several ways that Ms. Hu’s case lacked reasonable basis, Ms. Hu’s response really engaged with only one topic, the question of diagnosis. By citing medical records, Ms. Hu has shown that there is a reasonable basis for her claim that she suffered from myofasciitis. See exhibit 3 at 61-62 and exhibit 9 at 2, 6, 8-30.

However, the claim set forth in Ms. Hu’s petition is more than a claim that she suffered from myofasciitis. Ms. Hu also claims that an HPV vaccine *caused* her myofasciitis. For purposes of examining whether reasonable basis supports a causation-in-fact claim, special masters may use the Althen prongs as a structure, although the burden of proof for determining reasonable basis is lower.

One of the Althen prongs requires “a showing of a proximate temporal relationship between vaccination and injury.” Althen, 418 F.3d at 1278. Here, the Secretary argued that the latency between the third HPV vaccination and the onset of symptoms was approximately eight months. Resp’t’s Rep. at 5. In her reply, Ms. Hu did not dispute this calculation. She also did not explain how a latency of eight months is consistent with reasonable basis. See Pet’r’s Reply at 2 (discussing the medical records). She did not present any medical articles suggesting that a vaccination can cause myofasciitis that appears eight months later.

⁴ This Cottingham opinion is referred to as Cottingham XI.

Ms. Hu did not cite any cases in which special masters have found that a vaccination caused an injury that appeared eight months after vaccination. Special masters have tended to draw the line at approximately two months. See Cottingham X v. Sec'y of Health & Hum. Servs., No. 15-1291V, 2021 WL 6881248, at *47 (Fed. Cl. Spec. Mstr. Sept. 27, 2021), mot. for rev. denied, 159 Fed. Cl. 328 (2022), appeal docketed, No. 22-1737 (Fed. Cir. Apr. 28, 2022). Therefore, the long interval between the vaccination and the onset of symptoms weighs heavily against a finding of reasonable basis.

With respect to the Althen prongs regarding causation, Ms. Hu did not dispute the Secretary's assertion that neither a treating doctor nor an expert opined that the HPV caused Ms. Hu's alleged injury. This omission, by itself, does not cause a lack of reasonable basis. James-Cornelius, 984 F.3d at 1379.

Ms. Hu appears to have presented some information to support the claim that an HPV vaccine can cause myofasciitis by citing cases that have settled. While judicial *adjudications* might be considered a form of objective evidence that can support a finding of reasonable basis, see Sheller v. Sec'y of Health & Hum. Servs., No. 18-696V, 2022 WL 4075946, at *13-14 (Fed. Cl. Spec. Mstr. Aug. 15, 2022), mot. for rev. docketed (Sept. 14, 2022), settlements are not. Woods v. Sec'y of Health & Hum. Servs., 105 Fed. Cl. 148 (2012). Woods explained that without inquiry into the reasons for settlement, one cannot establish the strengths or weaknesses of a party's position. Id. at 152 (citing Pierce v. Underwood, 487 U.S. 522, 568 (1988)). Even if two settlements could be construed as presenting some evidence that an HPV vaccine can cause myofasciitis (Althen prong one), that information would not show that the HPV vaccine caused myofasciitis in Ms. Hu (Althen prong two). See Sheller, 2022 WL 4075946 at *14-17 (discussing uncertainty as how Althen prong two contributes or does not contribute to the reasonable basis analysis). Furthermore, that information would not demonstrate an HPV vaccine can cause myofasciitis many months after the injection.

In sum, the evidence in Ms. Hu's case does not pass the threshold for finding a reasonable basis supported the petition's claim that an HPV vaccine caused her to develop myofasciitis. Without this evidence, Ms. Hu cannot receive an award of attorneys' fees and costs. The evidence regarding reasonable basis does *not* include Ms. Hu's lack of participation in her case after (approximately) January

2021. See Simmons, 875 F.3d at 635 (discussing reasonable basis in the context of a petitioner who failed to assist his attorney in prosecuting his claim).⁵

V. Conclusion

Ms. Hu's evidence does not show a reasonable basis supported her petition's claim that an HPV vaccination caused her to suffer myofasciitis. Without establishing this predicate, Ms. Hu cannot be awarded attorneys' fees and costs. Therefore, her motion is DENIED.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including deadlines, is available at the website for the Court of Federal Claims.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master

⁵ While Ms. Hu's case contains more evidence than Simmons, the evidence in Ms. Hu's case fails to establish the reasonable basis for the claim set forth in the petition for the reasons explained in the text.